REMARKS

An RCE is being filed along with this Supplemental Amendment. The Examiner sent an Advisory Action dated April 5, 2004, stating that applicant's amendment after final, dated March 16, 2004, would not be entered because it presented new issues after final. The filing of the RCE by applicant removes the finality of the Examiner's last rejection; therefore, applicant's last amendment should be entered.

Additionally, in the Advisory Action, the Examiner indicated that the term "mycolyl-arabinogalactan-peptidoglycan" should not be abbreviated "MAPG" the first time it is used in the claims. In order to obviate this rejection, Applicant's have replaced the abbreviation with the full name of mycolyl arabinogalactin peptidoglycan (MAPG) in claim 1.

Finally, attached is an unsigned copy of a declaration of Dr. Alan Baxter. Dr. Baxter is the inventor of the present invention. Applicant's will provide a signed copy of this Declaration once it is received. Dr. Baxter's Declaration provides the requested additional data showing that mycolyl arabinogalactin peptidoglycan (MAPG) from *Mycobacterium* prevents the development of Type 1 diabetes.

For the foregoing reasons, a notice of allowance is solicited.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 229752000600.

Respectfully submitted,

Dated: September 15, 2004

By: _____

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Alan G Baxter.
Application No.	:	09/308,192
Filed	:	May 12, 1999
For	:	MYCOBACTERIUM CELL WALL COMPOSITIONS
	Examiner	: S Devi
	Art Unit	: 1645
	Docket No.	: 229752000600
	Date	: July 15, 2004

DECLARATION OF ALAN J. BAXTER, Ph.D.

Commissioner for Patents
Washington, D.C. 20231

The undersigned, Professor ALAN J. BAXTER, hereby declares:

1. I am a Scientist at Centenary Institute of Cancer Medicine and Cell Biology.

2. The following experiments were carried out under my supervision. We have shown that mycolyl arabinogalactin peptidoglycan (MAPG) from *Mycobacterium* prevents the development of Type I diabetes. This was confirmed in experiments performed in NOD/Lt mice in which two different strains of *Mycobacterium*, namely *Mycobacterium tuberculosis* and *Mycobacterium bovis,* were administered.

Female NOD/Lt mice spontaneously develop insulin-dependent diabetes mellitus (IDDM) by 35 weeks of age. The disease process involves a progressive preclinical phase of islet destruction which commences at 4-6 weeks of age and concludes with the onset of clinical diabetes between 14 and 35 weeks of age.

These mice were intravenously injected with a single dose of MAPG of either heat killed *Mycobacterium tuberculosis* or heat killed *Mycobacterium bovis* BCG. Of the mice injected with the *Mycobacterium tuberculosis,* none developed diabetes (see Figure 1, Appendix A), while of those injected with *Mycobacterium bovis*, less than 50% developed diabetes.

These studies demonstrate that MAPG from different *Mycobacterium* prevent the development of diabetes.

Additional experiments were performed in which a sub-component of MAPG, namely arabinogalactan peptidoglycan (APG) was administered to NOD/Lt mice. APG is MAPG following the removal of mycolic acids. In these experiments, animals were injected with either 1mg of BCG, 0.8mg MAGP, 0.8mg AGP or normal saline (see Figure 2, Appendix A). These experiments demonstrate that in addition to MAPG from different *Mycobacterium* strains being able to prevent the development of diabetes, components of MAPG, such as APG, can also prevent the development of diabetes.

3. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements, and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

ALAN J. BAXTER, Ph.D. Date

APPENDIX A

Figure 1 - Comparison of MAPG from *Mycobacterium bovis* BCG and *Mycobacterium tuberculosis* to prevent type 1 diabetes in NOD mice.

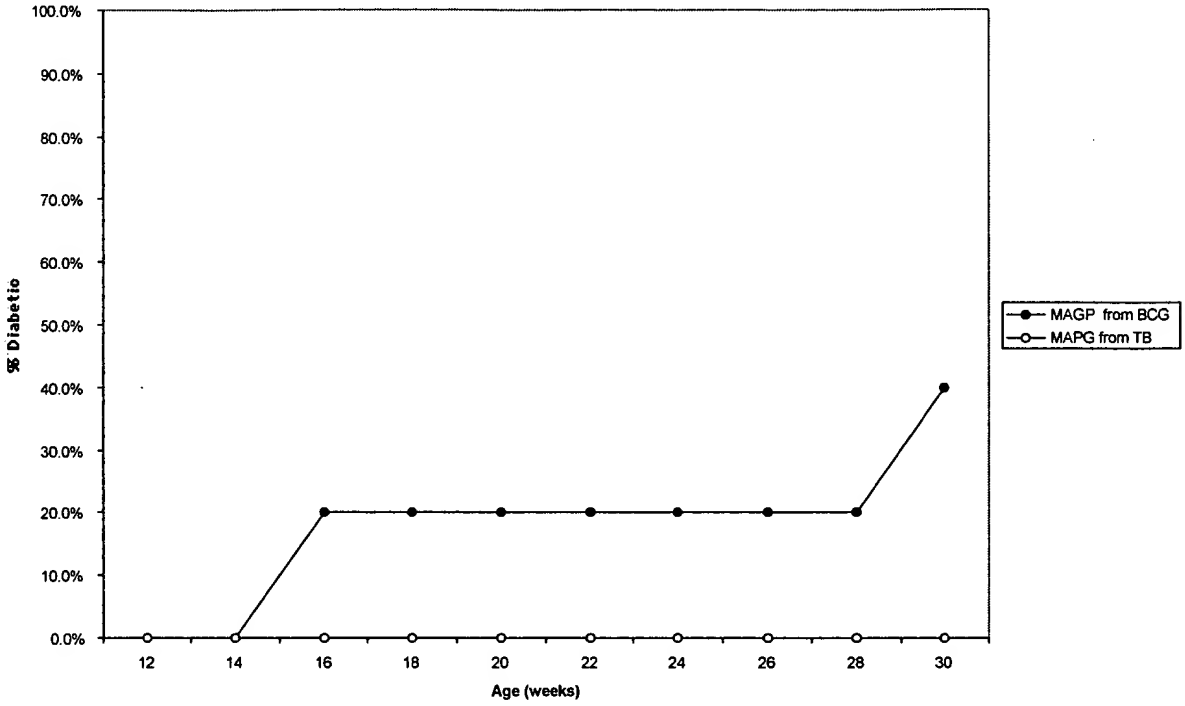

Figure 2 - Comparison of MAPG and APG from *Mycobacterium bovis* BCG to prevent type 1 diabetes in NOD mice